K093055 1/2

510(k) Summary
for the CSTS Screw

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the CSTS Screw

NOV 2 2 2010

Date Prepared: November 5, 2010

1. **Submitter:**
Ortho-Pro LLC
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Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone/Fax: 512-388-0199

2. **Trade name:** CSTS Screw
Common Name: Subtalar spacer
Classification Name: Screw, fixation, bone
21 CFR section 888.3040
HWC
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
OrthoPro STS Screw (K032682)
Futura Biomedical Arthrorisis Implant (K032902)

4. **Description of the device:**
The Ortho-Pro CSTS Screw consists of a threaded implant, designed to be inserted between the posterior and middle facets of the subtalar joint and corresponding instrumentation to facilitate insertion. The implant is conical in shape and incorporates a center cannula designed for use with a guide wire to facilitate proper placement of the implant. External flattened threads increase ease of insertion. It is available in five sizes, Ø8mm to Ø12mm in 1mm increments.

Materials:
Ti-6Al-4V alloy per ASTM F136
Commercially pure titanium per ASTM F67

Function:
The CSTS Screw blocks the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation.

5. **Substantial equivalence claimed to predicate devices**
CSTS Screw is substantially equivalent to the OrthoPro STS Screw (K032682) and Futura Biomedical Arthrorisis Implant (K032902) in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of the CSTS Screw to these predicate devices.

Device Name / Items	CSTS Screw	STS Screw	Futura Biomedical Arthrorisis Implant
Sponsor	OrthoPro	OrthoPro	Futura Biomedical
510(k) Number	--	K032682	K032902
Indications for Use	[1]	[2]	[3]

Device Name / Items	CSTS Screw	STS Screw	Futura Biomedical Arthrorisis Implant
Material	Ti-6Al-4V alloy per ASTM F136	Ti-6Al-4V alloy per ASTM F136	Ti-6Al-4V alloy per ASTM F136
CP Ti Plasma spray	Yes	No	No
Profile	Conical	Cylindrical	Conical
Thread	Yes	Yes	Yes
Non-threaded section	Yes	Yes	No
Cross holes	Yes	No, longitudinal grooves	Yes
Cannulated	Yes	Yes	Yes
Dimensions	Ø8-12mm	Ø6.5-11.5mm	Ø7-12mm
Sterile	No	No	?

6. **Intended Use:**

   The CSTS Screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela. It is appropriate for the following conditions:

   - Severely pronated foot
   - Calcaneal stance position greater than 5°
   - Manually correctable deformities
   - Mid-tarsal breech (arch pain)
   - Forefoot varus greater than 10°

7. **Non-clinical Test Summary:**

   The following tests were conducted:

   - Compressive testing

8. **Clinical Test Summary:**

   No clinical studies were performed

9. **Conclusions Nonclinical and Clinical:**

   The CSTS Screw is similar to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ortho-Pro, LLC
% The OrthoMedix Group, Inc.
% Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

NOV 2 2 2010

Re: K093055
Trade/Device Name: CSTS Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 5, 2010
Received: November 9, 2010

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV 2 2 2010

510(k) Number (if known): K093055

Device Name: **Ortho-Pro CSTS Screw**

NOV 2 2 2010

Indications for Use:

Ortho-Pro CSTS Screw
Indications for Use

The Ortho-Pro CSTS Screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela. It is appropriate for the following conditions:

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- Forefoot varus greater than 10°

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonutta J for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093055